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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/612,491

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/612,491	Applicant(s) SAADAT ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,16,26,27 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,16,26,27 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 11/25/2009.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5-7, 9, 16, 26, and 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Patent No. **6,736,828**) in view of **Walshe** (U.S. Patent No. **6,506,190**) and **Saadat** (U.S. Patent No. **7,186,262**).

Adams et al. disclose providing a delivery catheter or endoscope **16** having a needle **40** translatably disposed therein, a distal end, a stabilization device or tissue grasper **18** disposed at the distal end holding a tissue fold **14**, one or more anchors (either end of element **42**) disposed within the needle, advancing the delivery catheter into the gastroesophageal junction, engaging the stabilization device to a tissue wall of the gastroesophageal junction, advancing the needle through the catheter and a first tissue wall **46** and a second tissue wall **44**, ejecting first and second anchors (the ends of element **42**) from a distal tip of the needle, the anchors having a connection element **42** attached thereto, withdrawing the needle from the tissue walls whereby the connection element is extended through the tissue walls and the first and second

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anchors are placed on either side of the tissue walls to maintain the tissue fold (see abstract, Figures 1 and 5-7).

Although a gastroesophageal junction is accessed instead of tissue walls of a gastrointestinal lumen to create a tissue fold in Adams et al., it would have been obvious to one of ordinary skill in the art to apply the fundoplication method of Adams et al. to gastrointestinal tissue since it was well known in the art to manipulate gastric tissue by fundoplication to reduce the area of a gastrointestinal lumen for aiding obese patients in managing the amount of food desired and eaten.

Adams et al. also lack at least one of the anchors comprising a sleeve of braided material and an eyelet for attaching the anchor to a suture, although do teach “stent” or sleeve anchors **106**, **108** (Figures 16a-d), which are not necessarily braided or mesh material or have an eyelet. Also, Adams et al. do not expressly disclose translation of a fastener over the suture whereby a tension force is created on the suture and the tissue fold is maintained, wherein the fastener has a collar through which the suture extends.

Walshe teaches an anchor **27** made of a braided or mesh material that have an eyelet **404** or **61**, or holes that allow suture to attach or extend therethrough (Figures 9a-9b; col. 8, lines 14-29). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a braided material with an eyelet to the stent anchors of Adams et al., as taught by Walshe, in order to facilitate attachment with suture.

Saadat teaches translating a fastener **532** comprising a collar with a central channel through which a suture **506** extends whereby a tension force is created on the suture and said tissue fold is maintained (Figure 49A; col. 24, lines 42-51). It would

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have been obvious to one of ordinary skill in the art to modify Adams et al. by using a fastener and suture to the anchors of Adams et al., as taught by Saadat, so that the tension is maintained and the fastener may be translated over the suture after the tissue has been approximated to adjust tension on the tissue wall.

Regarding claim 3, Adams et al. do not disclose ejecting the anchor from the distal tip of the needle **40** by translating a push rod disposed in the needle.

Walshe teaches a push rod or plunger **5** that advances an anchor **20** into tissue and uncouples therefrom (Figures 16a-e). It would have been obvious to one of ordinary skill in the art to use a push rod to eject the anchor from the distal tip of the needle of Adams et al., as taught by Walshe, in order to facilitate advancement and positioning of the anchors.

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Patent No. **6,736,828**) in view of **Walshe** (U.S. Patent No. **6,506,190**) and **Saadat** (U.S. Patent No. **7,186,262**), as applied to claim 1 above, and further in view of **Laufer et al.** (U.S. Pub. No. **2004/0194790**).

Adams et al., Walshe and Saadat disclose the claimed invention except for the stabilization device being a coil with a sharpened tip and rotating the coil to engage the coil into the tissue wall.

Laufer et al. teach a stabilization device **740** disposed at the distal end comprising a coil **740**, or tissue holding element, having a sharpened tip and engaging the stabilization device to the tissue wall by rotating the coil (Figure 4A and page 3,

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paragraphs 79 and 83). It would have been obvious to one of ordinary skill in the art to provide a rotating coil stabilization device, as taught by Laufer et al., to Adams et al., Walshe and Saadat to facilitate engagement with tissue as the coil is biased in a distal direction to urge against tissue (page 1, paragraph 7).

4. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Patent No. **6,736,828**) in view of **Walshe** (U.S. Patent No. **6,506,190**) and **Saadat** (U.S. Patent No. **7,186,262**), as applied to claim 26 above, and further in view of **Gannoe et al.** (U.S. Patent No. **6,746,460**).

Adams et al., Walshe and Saadat disclose the claimed invention, including creating a tissue fold, except for creating a second tissue fold on an opposing tissue wall.

Gannoe et al. teach providing creating a second tissue fold on an opposing tissue wall (Figure 5A and col. 5, lines 23-37). It would have been obvious to one of ordinary skill in the art to provide a second tissue fold, as taught by Gannoe et al., to Adams et al. and Saadat since providing a multitude of folds depends on the desired results and the anchoring configuration or to facilitate further approximation of multiple sections tissue.

Response to Arguments

5. Applicant's arguments with respect to claims 1-7, 9, 16, 26-27, and 32-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734